

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESAL PRICE  
LITIGATION

MDL NO. 1456

THIS DOCUMENT RELATES TO ALL  
CLASS ACTIONS RELATING TO TRACK 1  
DEFENDANTS

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

**CLASS PLAINTIFFS' RESPONSE TO ASTRAZENECA PHARMACEUTICAL LP'S  
SUBMISSION OF RECENT CIRCUIT AUTHORITY**

Class Plaintiffs submit this brief response to the supplemental memorandum that AstraZeneca filed on April 4, 2008 (Dkt. No. 5198-2). AstraZeneca asserts that two recent appellate decisions, *In re: New Motor Vehicles Canadian Exp. Antitrust Litig.*, 2008 U.S. App. Lexis 6483 (1st Cir. Mar. 28, 2008), and *McLaughlin v. American Tobacco Co.*, 2008 U.S. App. Lexis 7093 (2d Cir. Apr. 3, 2008), support denial of Plaintiffs' pending motion to certify national Classes 2 and 3. Because the facts are so different here than in those two decisions, *New Motor Vehicles* and *McLaughlin* do not detract from certifying national classes in AWP.

**New Motor Vehicles**

AstraZeneca cites this case for the proposition that generalized expert testimony is not a substitute for evidence that each member of the class was indeed injured. AZ Br. at 3. Yet AstraZeneca overlooks the focus of the inquiry made by the First Circuit, the compelling similarity between the First Circuit's approach in *New Motor Vehicles* and the rigorous analysis that this Court has conducted into class certification, and the greater level of proof offered in the instant case.

The central issue posed by the First Circuit in *New Motor Vehicles* was “how far a district court should go in testing legal and factual premises at the class certification stage.” 2008 U.S. App. Lexis 6483, at \*29. The court reiterated *Smilow*’s well-known rule that a rigorous analysis is required, as well as *Mowbray*’s admonition that “a district court must formulate some prediction as to how specific issues play out.” *Id.* at \*37 (citing *Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 295 (1st Cir. 2000)). Where the facts are disputed and the theory of injury complex or novel, the district court must also “engage in a searching inquiry into the viability of that theory and the existence of the facts necessary for the theory to succeed.” *Id.* at \*56. Nonetheless, in “performing this predictive function and in ‘[e]xercising its broad discretion, . . . the district court must evaluate the plaintiff’s evidence . . . critically without allowing the defendant to turn the class-certification proceeding into an unwieldy trial on the merits.’” *Id.* at \*30 (quoting *In re PolyMedica Corp. Sec. Litig.*, 432 F.3d 1, 17 (1st Cir. 2005)).

Applying these standards to the case before it, the First Circuit was troubled by the incompleteness of the expert work and, therefore, the inability of the district court to evaluate the plaintiffs’ quest to prove causation through common evidence. It was the plaintiffs’ burden to demonstrate that the defendants’ actions resulted in an increase in dealer invoice prices in the United States. Nonetheless, the plaintiffs’ expert had not yet “fully answered such potentially relevant questions as how the size of the but-for influx of cars would be established or how large that influx would have to be to affect the national market sufficiently to raise effective dealer invoice prices and MSRPs.” *Id.* at \*60-61. Nor had the expert segregated the effects, if any, due to permissible vertical restraints from the effects of the allegedly unlawful horizontal conspiracy. *Id.*

As to damages, the court was skeptical that the plaintiffs could measure damages on an aggregate basis based on data that defendants purportedly possessed showing the consumer-level impact of the scheme. *Id.* at \*64-65. Notwithstanding the intuitive appeal of the inference that upward pressure on national pricing would raise prices paid by individual consumers, the expert had not yet completed his damages modeling. *Id.* at \*67. The court held that such a proffer did not suffice when assessing a complex theory of injury. Given the magnitude of alleged damage, and the fact that the discovery period had concluded since the district court issued its certification opinion, the First Circuit ordered the district court to more closely examine the end-product of the expert's work. *Id.* at \*68.

As AstraZeneca overlooks, this Court has already conducted a searching inquiry into the viability of Plaintiffs' causation and damages theory and the existence of the facts necessary for the theory to succeed. In doing so, the Court has repeatedly rejected AstraZeneca's pleas that the injury and damages determinations are too individualized for class treatment. The Court evaluated at trial the expert testimony of all parties, applied the *Daubert* standard and upheld Plaintiffs' "but-for" theory of causation, finding, among other things, that: (i) prices were lower in the post-AWP world resulting from the Medicare Modernization Act; (ii) "if there were transparent and accurate pricing, AWP's would have likely been much lower because they would have been related to true market prices"; and (iii) the 30% yardstick methodology was not only reliable and admissible but also "consistent with the undisputed evidence in the market establishing an industry-wide markup between WAC and AWP of 20% to 25%." *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 92 (D. Mass. 2007) ("AWP"). The Court has also consistently rejected AstraZeneca's repeated calls for an inquiry into the relevant knowledge of each and every class member (*see* AZ Br. at 4), as well as Defendants' challenge

to aggregate damages, finding that Dr. Hartman's calculation of aggregate damages for the class was sufficiently reliable and appropriate based on the record. *Id.* at 93.

Accordingly, the deficiencies plaguing the plaintiffs' incomplete proffer in *New Motor Vehicles* are not present in Plaintiffs' completed theory of injury and damages that already prevailed at trial here. The First Circuit in *New Motor Vehicles* called for a searching inquiry into the viability of complex theories of injury and damages before a court certifies a class. By holding a trial and maintaining class certification in the face of Defendants' post-trial challenge thereto, this Court has already conducted a much deeper inquiry than that required by the First Circuit in *New Motor Vehicles*. And that detailed inquiry resulted in a finding of fact that Plaintiffs' theory was not only viable but superior to the theories advanced by Defendants. In sum, this Court is already applying the very rigorous analysis called for by *New Motor Vehicles*, and Plaintiffs adequately meet the standard for certifying national Classes 2 and 3.<sup>1</sup>

### **McLaughlin**

#### **1. Reliance and Causation**

The district court in *McLaughlin* had certified a class of consumers who had purchased "Light" cigarettes. The plaintiffs claimed that defendants' implicit representation that Lights were healthier led consumers to buy Lights in greater quantity than they otherwise would have and at an artificially high price over the course of a 37-year period. 2008 U.S. App. Lexis 7093, at \*5. In other words, believing the Lights to be safer than regular cigarettes, the plaintiffs and the class were denied a benefit of the bargain when they later learned that Light cigarettes were

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<sup>1</sup> AstraZeneca also contends that *New Motor Vehicles* stands for the proposition that state-specific classes must be created with a separate representative for each class. AZ Br. at 5-6. This is a new position never before argued by AstraZeneca on this motion and therefore should be rejected on that basis alone. But, in any event, the First Circuit in *New Motor Vehicles* made no such holding and did not evaluate the district court's choice of law decisions or state class groupings. Moreover, separate class representatives are not needed where, as here, state laws can be grouped by common elements.

not safer than regular cigarettes (even though the price of Lights and regular cigarettes were the same).

The Second Circuit reversed class certification, because the plaintiffs could not demonstrate RICO reliance and causation through the use of common proof. The nature of the plaintiffs' claims – focused as they were on the very subjective issue of consumer choice – required a highly individualized level of proof. As the court explained, “[i]ndividualized proof is needed to overcome the possibility that a member of the purported class purchased Lights for some reason other than the belief that Lights were a healthier alternative – for example, if a Lights smoker was unaware of that representation, preferred the taste of Lights, or chose Lights as an expression of personal style.” *Id.* at \*14. The court also held that the *Basic v. Levinson* presumption of reliance, or some variation of it, could not apply because it could not be assumed that individual smokers were all aware of the defendants' misrepresentations and that the market at large had internalized the misrepresentations to such an extent that all plaintiffs can be said to have relied on it. *Id.* at \*17. Moreover, each plaintiff could have chosen to purchase Lights for any number of reasons having nothing to do with the misrepresented and implicit health claim, including a preference for taste, peer inference or other personal preference. *Id.* at \*20-21. For these reasons, the court held that reliance could not be proven in the aggregate. And these same challenges precluded the plaintiffs' ability to prove loss causation on a class-wide basis. *Id.* at \*24-25.

Contrary to AstraZeneca's assertion (*see* AZ Br. at 7), the Second Circuit in *McLaughlin* did not adopt a blanket rule that a fraud class action cannot be certified when individual reliance is required. Indeed, the Second Circuit expressly rejected that approach from the Fifth Circuit. 2008 U.S. App. Lexis 7093, at \*19 (rejecting *Castano v. American Tobacco Co.*, 84 F.3d 734,

745 (5th Cir. 1996)). Instead, the court held that proof of reliance by circumstantial evidence may suffice under certain conditions, citing as an example making a payment as proof of reliance upon a financial representation. *Id.* at \*20-22 & n.7. Indeed, the court cited some of the same opinions that Plaintiffs here have offered to this Court in support of certifying claims under those few UDTPAs that require reliance, including *Chisolm v. TranSouth Fin. Corp.*, 194 F.R.D. 538, 561 (E.D. Va. 2000), and *Klay v. Humana, Inc.*, 382 F.3d 1241 (11th Cir. 2004). The court also observed that “some fraud actions do appear within a contemplation of Rule 23’s drafters,” citing the Advisory Committee Notes to Rule 23(b)(3): “[A] fraud perpetrated on numerous persons by the use of similar misrepresentations may be an appealing situation for a class action, and it may remain so despite the need, if liability is found, for separate determination of the damages suffered by individuals within the class.” *McLaughlin*, 2008 U.S. App. Lexis 7093, at \*19.

Thus, *McLaughlin*, even if it were binding on this Court (and it is not), does not bar certification of class claims requiring reliance in every case. The door remains open, as many other courts have recognized, for a demonstration of reliance based on class-wide evidence.<sup>2</sup>

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<sup>2</sup> See, e.g., *Klay v. Humana, Inc.*, 382 F.3d at 1259 (circumstantial evidence that is common to the whole class can be used to show reliance) (RICO case); *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 179-180 & n.21 (3d Cir. 2001) (recognizing that “an illegal price-fixing scheme presumptively damages all purchasers of a price-fixed product in an affected market[,]” and that in “overcharging cases that warrant a presumption of reliance,” plaintiffs meet the causation element where “they sustain economic loss by reason of the alleged conduct.”) (quoting *Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 454 (3d Cir. 1977)); *Thorogood v. Sears Roebuck & Co.*, 2007 U.S. Dist. Lexis 81035, at \*8 (N.D. Ill. Nov. 1, 2007) (noting that reliance can be presumed based on class-wide evidence that defendant marketed its dryers on a uniform, standard basis of being made of stainless steel, when they were not; class certified under UDTPAs of 29 states); *Grider v. Keystone Health Plan Central, Inc.*, 2006 U.S. Dist. Lexis 93085, at \*64-65 (E.D. Pa. Dec. 21, 2006) (plaintiffs will be able to prove class-wide reliance based upon circumstantial evidence in case where defendants allegedly intentionally misrepresented, and failed to disclose, internal HMO policies and practices that were designed to systematically reduce, deny, and delay reimbursement payments to plaintiffs and their business) (RICO case); *Negrete v. Allianz Life Ins. Co. of N. Am.*, 238 F.R.D. 482, 491 (C.D. Cal. 2006) (“If class plaintiffs can show that generalized methods of proof are available to show that uniform representations were made to all class members which were misleading because they failed to disclose that all of the annuities at issue were worth less than the purchase prices paid for them or are fundamentally inferior to comparable products, then plaintiffs may be able to show that they have available a means of demonstrating reliance on a class-wide basis.”) (RICO case); *Chisolm v. TranSouth Fin. Corp.*, 194 F.R.D. at 560-63 (finding that the very fact that class members made deficiency payments after repossession constituted circumstantial proof of reliance and framing the issue of whether reliance was reasonable as an objective inquiry common to the entire class); *Garner v. Healy*, 184 F.R.D. 598, 602 (N.D. Ill. 1999) (courts typically hold that

Furthermore, the reliance issues in the instant price benchmarking case are not even remotely similar to the type of subjective consumer choices that were at issue in *McLaughlin*. Here, Plaintiffs' and the class members' reliance on the uniform AWP pricing representation presents a much more objective inquiry that is susceptible to common proof. As the Court has already found, the evidence at trial demonstrated that market participants – that is, Plaintiffs and class members – believed that AWP was a consistent and reliable benchmark for use in negotiating drug pricing and, therefore, relied on it as such.<sup>3</sup> As the Massachusetts trial demonstrated, Plaintiffs' claims are principally susceptible of common proof. The reliance issue will play out no differently at the next trial for those few state UDTPAs that actually require reliance.<sup>4</sup>

## 2. Aggregate Damages

AstraZeneca also cites *McLaughlin* for the proposition that Plaintiffs here cannot prove injury or aggregate damages on a class-wide basis and that each class member must prove his or her (or its) damages individually. AZ Br. at 8-9. Once again, because the facts, as well as expert damages modeling, are so different here, *McLaughlin* does not help AstraZeneca. Unlike Plaintiffs' damages model in AWP, the plaintiffs in *McLaughlin* had not developed a manner by

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individual reliance questions do not predominate where the fraud was perpetrated in a uniform manner); *Cullen v. Whitman Med. Corp.*, 188 F.R.D. 226, 234-35 (E.D. Pa. 1999) (proof of individual causation or reliance unnecessary; if the plaintiffs can prove that the school was a "complete sham," then a fact finder can infer from the evidence that anyone who paid tuition and attended the school suffered damage) (RICO, state UDTPA and common law fraud case); *Peterson v. H & R Block Tax Servs.*, 174 F.R.D. 78, 84-85 (N.D. Ill. 1997) ("[C]ourts will presume class members' reliance when it is logical to do so or when the complaint's allegations make reliance apparent.") (RICO case); see also *Systems Mgmt. v. Loiselle*, 303 F.3d 100, 104 (1st Cir. 2002) ("Reliance is doubtless the most obvious way in which fraud can cause harm, but it is not the only way: Loiselle does not deny that a reasonably predictable consequence of his mailings was, by deceiving the college, to enable him to continue to underpay his workers.").

<sup>3</sup> An example from the Court's findings: "[T]hroughout the class period, most knowledgeable insiders understood that AWP did not reflect the average sales price to providers, but that it bore a formulaic relationship to WAC of a 20 to 25 percent markup. In addition, payors were aware there was some discounting from WAC." *In re AWP*, 491 F. Supp. 2d at 40.

<sup>4</sup> Only five UDTPAs at issue here require reliance: Arizona, Indiana, North Carolina, Pennsylvania and Wyoming.

which a standardized overcharge based on the actual damage caused by the defendants' conduct could be determined.

The plaintiffs in *McLaughlin* posited two methods of calculating damages: (i) the loss of value method, positing that plaintiffs should have paid less for Light cigarettes because they did not receive the benefit of their bargain, to wit, healthier cigarettes (2008 U.S. App. Lexis 7093, at \*29-30); and (ii) the price impact method, asserting that defendants would have been required to reduce their prices if the truth about their products had been known and the concomitant demand had been reduced (*id.* at \*34). The court found that an unacceptable level of speculation was inherent in both proposed methodologies.

In the loss of value method, the plaintiffs would have had to estimate what a consumer would have paid for a healthy cigarette. However, the plaintiffs' expert was unable to establish the purported loss of value. He asked consumers to compare between a "genuine" light cigarette that reduced health risk and a "misrepresented" light cigarette that was no different than conventional cigarettes, and survey respondents reported a "non-zero" loss in value. This led the court to determine that plaintiffs' theory was "pure speculation." *Id.* at \*33.

In the price impact method of evaluating damages, the plaintiffs would have to estimate how much class members would have been willing to pay for Light cigarettes had the truth been known. But the plaintiffs had failed to provide a reasonable means of estimating that price since (i) Lights had always been priced the same as regular smokes, and (ii) no drop in demand for Lights occurred once a monograph was published reporting that Lights did not reduce the risks of smoking. *Id.* at \*34-35.

In both proposed methodologies, the court held, there was no method for determining an *actual* overcharge. Instead, the plaintiffs proposed a method of determining a hypothetical



overcharge and then proposed a method by which those with varying degrees of strengths of claims might make claims for damages at the claims stage, leading to the payment of damages that would not reflect the defendants' actual liability or, worse, would "bear[] little or no relationship to the amount of economic harm actually caused by defendants." *Id.* at \*39-40.

Contrary to the salient flaws present in the causation and damages model presented by the plaintiffs in *McLaughlin*, here Plaintiffs' model reflects **actual** overcharges and **actual** harm caused by each Defendant. Drug-by-drug, Dr. Hartman has determined the amount of the overcharge caused by Defendants' publication of a false AWP based on a yardstick methodology that, the Court has already ruled, was not only reliable and admissible but also "consistent with the undisputed evidence in the market establishing an industry-wide markup between WAC and AWP of 20% to 25%." *In re AWP*, 491 F. Supp. 2d at 92. Speculation does not underpin these calculations, and the Court has found that Dr. Hartman's calculation of aggregate damages for the class was sufficiently reliable and appropriate based on the record. *Id.* at 93. *McLaughlin* does not help AstraZeneca.

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**CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE**

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on April 11, 2008, I caused copies of **CLASS PLAINTIFFS' RESPONSE TO ASTRAZENECA PHARMACEUTICAL LP'S SUBMISSION OF RECENT CIRCUIT AUTHORITY** to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

**/s/ Steve W. Berman**

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